REMARKS

The Office Action mailed October 23, 2006 has been received and reviewed. Applicants propose to amend claims 1 and 10, cancel claim 2, and add new claim 14. Support for the amendments to claim 1 may be found in claim 2 and paragraph [0009] of the as-filed specification. The amendment to claim 10 is only for formalistic reasons. Support for new claim 14 may be found in claims 1 and 11-13 of the as-filed application. No new matter has been entered. The amendments and claim cancellation are made without prejudice or disclaimer. Claims 1, 3-8, and 10-14 are pending herein. Claims 1, 3-8, and 10-13 stand rejected. Reconsideration is respectfully requested.

1. Claim Rejections and 35 U.S.C. § 112

Applicants thank the Examiner for withdrawal of the 35 U.S.C. § 112 rejections.

2. Claims Rejections and 35 U.S.C. § 102

Claims 1-7 and 10-13 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 01/72831 (IDS reference) as evidenced by Merck Index (17th ed. 1999, p.1145, 1146, 1841-1848, 2539, & 2550) and Dwinnell *et al.* (Atlas of Diseases of the Kidney, Ch. 12, 1999) ("Dwinnell"). Claim 2 is canceled, thereby mooting the rejection as to that claim. Specifically, it was thought that reducing blood urea nitrogen ("BUN") concentration is an inherent property of the oligopeptide composition consisting of SEQ ID NO:2. *Office Action mailed October 23, 2006, page 3.*

Regarding claim 1, as amended, applicants respectfully submit that it is irrelevant whether the LQGV or AQGV disclosed in WO 01/72831 would inherently reduce BUN concentration. Claim 1 is directed to a method of treating acute renal failure. The claimed method is a novel use of AQGV and other oligopeptides. A novel use may be patentable. See, for example, M.P.E.P. § 2112.02 which states that "[t]he discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using." WO 01/72831 discloses, *inter alia*, that oligopeptides AQGV and LQGV have an anti-shock effect. *See Table 2, page 61.* The experiments with AQGV and LQGV would not necessarily have resulted in treatment of acute renal failure. WO 01/72831 does not

mention acute renal failure. Therefore, claim 1 is novel.

Applicants further submit that WO 01/72831 does not inherently disclose a method of treating acute renal failure. With respect to inherency, M.P.E.P. § 2112 provides:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. *In re Rijckaert,* 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) . . . 'To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'' *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1991).

Septic shock may cause acute renal failure in some cases. However, the Office has not established that every case of septic shock will necessarily cause acute renal failure. On the contrary, the Office has only asserted that the Merck Index teaches that a major cause of renal failure is septic shock. *Office Action mailed October 23, 2006, page 3.* The Merck Index at page 1842 lists septicemia as one of 34 "major" causes of acute renal failure. The Merck Index does not disclose that acute renal failure necessarily follows septic shock in every case. Thus, it does not establish that every case (or even a majority of cases) of septic shock result in acute renal failure. Additionally, on page 3, WO 01/72831 provides a definition of septic shock - "[w]hen this syndrome results in hypotension or multiple organ system failure (MOSF), the condition is called sepsis or septic shock." Although it is possible that the kidneys could be one of the organs to fail, clearly numerous other organs could fail without the kidneys failing (*e.g.*, the heart). Tellingly, WO 01/72831 discloses experiments related to the heart and the spleen, and not related to the kidneys. *See, e.g., pages 65-67.* The Office has not established that septic shock will necessarily cause acute renal failure in every case. Thus, the Office has not established that WO 01/72831 inherently discloses a method of treating acute renal failure. Therefore, claim 1 is novel, and claims 3-7 and 10-13 are novel for at least the reason of depending from novel claim 1.

Additionally regarding claims 12 and 13, applicants respectfully submit that extrinsic

evidence has been improperly used in making the 35 U.S.C. § 102 rejections. M.P.E.P. § 2131.01(III) provides that extrinsic "evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." The evidence from the Merck Index does not make clear that the subjects' kidneys in WO 01/72831 were not producing more than ½ ml of urine per hour per kilogram of body mass of the subject. Likewise, the evidence from the Merck Index does not make clear that the subjects in WO 01/72831 had a serum potassium level greater than 6.5 mmol per liter serum. The Merck Index does not relate to the specific experiments of WO 01/72831. Therefore, the Merck Index cannot constitute extrinsic evidence under 35 U.S.C. § 102 for the experiments of WO 01/72831. Therefore, for this additional reason, claims 12 and 13 are not anticipated.

Applicants respectfully request withdrawal of the 35 U.S.C. § 102 rejections.

Claims 1-5, 7, 8, and 10-13 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by US 2004/0013661 (IDS reference) as evidenced by Merck Index (17th ed. 1999, p.1145, 1146, 1841-1848, 2539, & 2550), Merriam Webster's Dictionary (p. 82) and Dwinnell *et al.* (Atlas of Diseases of the Kidney, Ch. 12, 1999) ("Dwinnell"). Claim 2 is canceled, thereby mooting the rejection as to that claim. Specifically, it was thought that reducing blood urea nitrogen ("BUN") concentration is an inherent property of the oligopeptide composition consisting of SEQ ID NO:2. *Office Action mailed October 23, 2006, page 4.*

Regarding claim 1, as amended, applicants respectfully submit that under 35 U.S.C. § 102(e), it is irrelevant whether the LQGV or AQGV disclosed in US 2004/0013661 would inherently reduce BUN concentration if administered to a subject. Claim 1 is directed to a method of treating acute renal failure. The claimed method is a novel use of AQGV and other oligopeptides. US 2004/0013661 discloses, *inter alia*, that oligopeptides AQGV and LQGV may be used for treatment of sepsis/SIRS. *See paragraph [0041].* However, it is impossible that the experiments in US 2004/0013661 inherently reduced BUN concentration of a subject or treated acute renal failure. The experiments in US 2004/0013661 relate to, *inter alia*, synthesis of gene-regulatory peptides and the testing of gene-regulatory peptides in cells. *See paragraphs [0049] to [0057].* It is impossible for the cells in the experiments to undergo acute renal failure as the

cells do not have kidneys or blood. Therefore, it is impossible that those experiments would necessarily have resulted in treatment of acute renal failure or reduced the BUN concentration of a subject. Additionally, US 2004/0013661 does not mention BUN concentration or acute renal failure. Therefore, US 2004/0013661 does not inherently anticipate claim 1. Claims 3-5, 7, 8, and 10-13 are novel for at least the reason of depending from novel claim 1.

Additionally regarding claims 12 and 13, applicants respectfully submit that extrinsic evidence has been improperly used in making the 35 U.S.C. § 102 rejections. The experiments in US 2004/0013661 do not involve administering AQGV or LQGV to subjects with kidneys. Therefore, it is impossible for the evidence in the Merck Index to make clear that a subject's kidneys in US 2004/0013661 were not producing more than ½ ml of urine per hour per kilogram of body mass of the subject. Likewise, it is impossible for the evidence in the Merck Index to make clear that subjects in US 2004/0013661 had a serum potassium level greater than 6.5 mmol per liter serum. Additionally, the Merck Index does not discuss the specific experiments of US 2004/0013661. Therefore, the Merck Index cannot constitute extrinsic evidence under 35 U.S.C. § 102 for the experiments of US 2004/0013661. Thus, for this additional reason, claims 12 and 13 are not anticipated.

Applicants respectfully request withdrawal of the 35 U.S.C. § 102 rejections.

3. Provisional Double Patenting

Claims 1-8 and 10-13 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as assertedly being unpatentable over claims 1-13 of copending Application No. 11/249,541. Claim 2 is cancelled thereby mooting the rejection as to that claim. Applicants submit that claims 1, 3-8, and 10-13 are otherwise allowable, and that no other rejections other than the provisional rejections are outstanding. Therefore, applicants respectfully request the provisional rejections dropped and the case passed for issue.

4. Entry of Amendments and New Claim

Applicants submit that the claim amendments should be entered as they should place the application in condition for allowance. Additionally, the claim amendments do not require any further search. The subject matter of claim 2 should have been included in the initial search

conducted by the Office. *M.P.E.P. § 904.*

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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